FAQs After iRIS Go-Live

May 21, 2018

We will add to this list of FAQs in the coming days.

Q: Do I need to submit a migration amendment in order to submit a safety event?  
A: No, a migration amendment is not required.

Q: Do I need to submit a Migration Amendment to the IRB? A migration amendment involves the completion of the full iRIS application, and the information entered in iRIS must be the same as the information that appeared in eIRB.

A: Submit the Migration Amendment only if you have an upcoming Continuing Review or Amendment that you need to submit. Wait to submit the Migration Amendment if you do not have a Continuing Review or Amendment that you need to otherwise submit now.

If you have a NEW STUDY under IRB review, the IRB will return the study to the study team to complete the iRIS application, with or without other mods.

If you have an Amendment already in process with the IRB, the IRB will return the study to the study team to complete the iRIS application, with or without other mods.

If you have a Continuing Review (Renewal) that was submitted in eIRB, you must submit a separate Migration Amendment before the IRB can complete the review. A new Continuing Review does not need to be submitted.

Q: My NEW STUDY had not reached the IRB yet before May 18. Where is it now?

A: The study has been returned to Draft (Presubmission) state. The iRIS application needs to be fully completed and the study resubmitted. CRU and Specialty Committees should fast-track studies that they have already reviewed in our old system, eIRB.

Q: I have an EXEMPT study (declared exempt from further IRB review). Do I need to submit a Migration Amendment?

A: Migration Amendments are not required for EXEMPT studies. If you need to submit an amendment in the future for the exempt study, you can update all information at that time in a normal amendment.

Q: Do I need to submit a migration amendment before closing my study?

A: No, a migration amendment is not required. The final report form in iRIS may prompt you to complete incorrect questions because the application does not exist in iRIS. Please answer
only applicable questions.